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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,245	06/20/2003	Henry Nita	PAT-1505	6687

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EXAMINER	
HUH, BENJAMIN	
ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	10/601,245	NITA ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,10-17,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 10-17, 36-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 10-13, & 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Passafaro et al (US Patent No. 5324255). The Passafaro reference discloses an ultrasound catheter in figures 1-13 comprising a Y-connector having a distal end seen as part of section 38 in conjunction with element 72, an elongate flexible catheter body 12 having a proximal end connected to the distal end of the Y-connector 38, a distal end, and a main lumen 100 extending longitudinally therethrough; an ultrasound transmission member 28 extending longitudinally through the main lumen 100 of the catheter body, the ultrasound transmission member 28 having a distal end positioned at the distal end of the catheter body; and a guidewire tube 60 defining a lumen extending longitudinally through a portion of the main lumen and terminating in a guidewire port 84 that is located at a position between the distal and proximal ends of the catheter body and closer to the proximal end of the catheter body than to the distal end of the catheter body.

With respect to claim 2, further including a Y-connector seen as part of section

38 in conjunction with element 72 connected to the proximal end of the catheter body, with the guidewire port 84 positioned adjacent the Y-connector, see figure 2.

With respect to claim 10, an elongate flexible catheter body 12 having a proximal end, a distal end, and a main lumen 100 extending longitudinally therethrough; an ultrasound transmission member 28 extending longitudinally through the main lumen of the catheter body, the ultrasound transmission member 28 having a distal end positioned at the distal end of the catheter body; and a guidewire tube 60 extending longitudinally through a portion of the main lumen and positioned at about the center of the main lumen, a guidewire 86 positioned inside the guidewire tube, and wherein the ultrasound transmission member 28 is positioned outside the guidewire tube 60, wherein the examiner would like to note that the ultrasound transmission member 28 can be seen to be positioned inside and outside the guidewire tube, also see figures 1-2, 4-5, & 7.

With respect to claim 11, wherein the guidewire lumen defined by element 60 terminates in a guidewire port 84 that is adjacent the proximal end of the catheter body, see figures 4-5.

With respect to claim 12, wherein the catheter has a distal head 104, and wherein the guidewire tube 60 is affixed to the distal head 104, see figure 4.

With respect to claim 13, wherein the guidewire tube 60 is positioned at about the center of the distal head 104, see the distal end of the guidewire tube 60, see figure 4.

Claims 1-2 & 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nita (US patent No. 5312328). The Nita reference discloses an ultrasound catheter in figures 1, 6, & 6b comprising a Y-connector having a distal end, an elongate flexible catheter body 20b having a proximal end connected to the distal end of the Y-connector, a distal end, and a main lumen 22b extending longitudinally therethrough; an ultrasound transmission member 24 extending longitudinally through the main lumen 22b of the catheter body, the ultrasound transmission member 24 having a distal end positioned at the distal end of the catheter body; and a guidewire tube 156 defining a lumen extending longitudinally through a portion of the main lumen and terminating in a guidewire port 160 that is located at a position between the distal and proximal ends of the catheter body and closer to the proximal end of the catheter body than to the distal end of the catheter body, a guidewire tube extending longitudinally through a portion of the main lumen and into the proximal section of the bore of the distal head, the guidewire tube terminating before the distal section of the bore of the distal head.

With respect to claim 10, see figures 6 & 6b, an elongate flexible catheter body 20b having a proximal end, a distal end, and a main lumen 22b extending longitudinally therethrough; an ultrasound transmission member 24 extending longitudinally through the main lumen of the catheter body, the ultrasound transmission member 24 having a distal end positioned at the distal end of the catheter body; and a guidewire tube 156 extending longitudinally through a portion of the main lumen and positioned at about the center of the main lumen, a guidewire 42 positioned inside the guidewire tube, and wherein the ultrasound transmission member 24 is positioned outside the guidewire

tube 156, wherein the examiner would like to note that the ultrasound transmission member 24 can be seen to be positioned inside and outside the guidewire tube.

Claims 1-2, 10-17, 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Nita (US Patent No. 5989208). The Nita reference discloses an ultrasound catheter in figures 1-3 comprising a Y-connector having a distal end, an elongate flexible catheter body 12 having a proximal end connected to the distal end of the Y-connector, a distal end, and a main lumen 18 extending longitudinally therethrough; an ultrasound transmission member 30 extending longitudinally through the main lumen 18 of the catheter body, the ultrasound transmission member 30 having a distal end positioned at the distal end of the catheter body; and a guidewire tube 80 defining a lumen extending longitudinally through a portion of the main lumen and terminating in a guidewire port 86 that is located at a position between the distal and proximal ends of the catheter body and closer to the proximal end of the catheter body than to the distal end of the catheter body, a guidewire tube extending longitudinally through a portion of the main lumen and into the proximal section of the bore of the distal head, the guidewire tube terminating before the distal section of the bore of the distal head.

With respect to claim 10, see figures 1-3, an elongate flexible catheter body 12 having a proximal end, a distal end, and a main lumen 18 extending longitudinally therethrough; an ultrasound transmission member 30 extending longitudinally through the main lumen of the catheter body, the ultrasound transmission member 30 having a

distal end positioned at the distal end of the catheter body; and a guidewire tube 80 extending longitudinally through a portion of the main lumen and positioned at about the center of the main lumen, a guidewire 28 positioned inside the guidewire tube, and wherein the ultrasound transmission member 30 is positioned outside the guidewire tube 80, wherein the examiner would like to note that the ultrasound transmission member 30 can be seen to be positioned inside and outside the guidewire tube.

With respect to claim 36, see figure 12, which discloses a sonic connector 200 for connecting the ultrasound transmission member to an ultrasound generating device, the sonic connector having a distal bore 224 to which the proximal-most end of the transmission member 30 is attached; a central portion 220 having a flat proximal face, the face seen as the section before the threaded portion 226; a threaded portion 226 extending and spaced-apart from the flat proximal face, the threaded portion 226 attached to the ultrasound generating device; and wherein the distal bore terminates distal of the flat proximal face and the threaded portion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passafaro et al (US Patent No. 5324255) as applied to claim 1 & 10 above and further

in view of Nita et al (US Patent No. 5312328). The Passafaro reference also discloses the distal head 104 having a bore with a proximal section and a distal section that has an inner diameter that is smaller than the inner diameter of the proximal section of the bore see figures 4, 4a, & 8-9. Now even though Passafaro does not explicitly disclose a guidewire tube extending longitudinally through a portion of the main lumen, and into the proximal section of the bore of the distal head, the guidewire tube terminating before the distal section of the bore of the distal head attention is directed to Nita. The Nita reference teaches the use of a guidewire tube 156 that extends through the bore and terminating before the distal section of the bore in figures 6 & 6b. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to utilize the teachings of Nita in the device of Passafaro in order to facilitate the movement of the guidewire through the device.

Response to Arguments

Applicant's arguments with respect to claims 1-2, 10-17, 36-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER
Kevin C. Sirmons